UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,619	10/21/2002	Kojiro Takahashi	TAKAHASHI30	8322

1444 7590 03/10/2003

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER
WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,619	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

; **DETAILED ACTION**

Specification

The abstract of the disclosure is objected to because of the used of phraseology often used in patent claims e.g., "comprises". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: typographical, idiomatic and grammatical errors too numerous to mention specifically. (The application is a literal translation of the foreign application).

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: for example, page 2, line 1 "and affecting with RT…" and paragraph 4, "….as recited in claim 3 and synthetic immobilizing a sense portion on a support by utilizing the anti-sense portion……"; "modificated" and "replica". See also, the claims.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The

substitute specification filed must be accompanied by a statement that it contains no new matter.

Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, this claim has not been further treated on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

The specification fails to describe a utility for the claimed ssDNA immobilized library. The disclosure at page 17 simply recites the "possibility of use" of the library. The possibility of use is not a specific utility as required by the law. There is not a single example to demonstrate the possible use of the library.

The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial

> utility. . . . [u]nless and until a process is refined and developed to this point-**where specific benefit exists in currently available form**-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . In *Brenner*, the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible compounds the utility of which has also not been identified. *Brenner*, 148 USPQ at 690. (Emphasis ours).

"Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility….A patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Claim 8 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a written description for the different methods of making different nucleic acid compounds i.e., cDNA, gDNA, ss gDNA library. The specification provides a general description of an apparatus which contains these immobilized nucleic acids. It is not apparent from this disclosure the kind, if any, of even a single cDNA, gDNA, ss gDNA library that has been made utilizing the methods as claimed or disclosed. [The crux of the invention apparently resides in an apparatus that produces an immobilized nucleic acid.]

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Each of the methods recites only a single step. It is not clear from said single step how a product is obtained. The claims recite terminologies such as "affecting RT", "modificated" (claim 6), "ligasing", "respective enzyme portion" (claim 3) and others terms that are not art-recognized. "Affecting" is not a positive, manipulative process step.

B. It is not clear whether claim 2 is a continuation step of claim 1. The phrase "a step" is redundant. It is suggested that applicants delete said phrase.

C. Claims 4 and 5 broaden the base claim 3 in the recitation of an immobilized sense portions of the gDNA recited

in claim 3. Claim 3 does not identify a sense or anti-sense portion of the gDNA library.

D. Claim 6 is indefinite in the recitation of "is previously chemically modificated".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 6,489,111 ('111 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed methods reciting a single broad step encompasses the specific method of the '111 Patent. [The instant disclosure discloses a similar apparatus containing the instant

method]. The '111 Patent recites broadly a DNA. However, the '111 disclosure defines DNA as any one of cDNA, gDNA and ss gDNA as in the instant claimed specific DNAs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 4, 6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Takahishi et al (US PAT.NO. 6,489,111).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Takahisi discloses at col. 4, line 29 up to col. 5, line 13 a method of making a cDNA (complementary DNA), comprising extracting mRNA (total mRNA) from tissues and cells and mRNA is hybridized with oligo-dT. After hybridization, cDNA is synthesized by Reverse Transcriptase (RT). The cDNA are reacted and immobilized so as to extend toward the terminal 5' of hybridized oligo-dT. Hybridized solution of synthesized immobilized cDNA and mRNA is heated in order to dehybridize mRNA. A purified immobilized cDNA library in one chain DNA condition is prepared (see FIG. 7). In the case of gDNA library, immobilized oligonucleotides target restrictive enzymes (see. FIG. 8) are immobilized on surfaces of the diamond chips 41 as

for oligo-dT. For chemical immobilization, the reaction solution is exchanged for reaction solution including hybridized oligonucleotides with target restrictive enzymes. After hybridization with oligonucleotides, the reaction solution is heated, so as to cut the restrictive enzymes of the semi-immobilized oligonucleotides. Therefore, the specific method of Takahashi employing specific library fully meets the broad claimed single step method and library.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schena et al (PNAS, 1996) or Schmidt et al (US 6,225,077 (102e).

Schmidt discloses at col. 13, lines 5-31 a process of making a cDNA comprising immobilizing mRNA by hybridisation to biotinylated poly-T. This allows capture of the population after reverse transcription of the mRNA onto avidinated glass beads. In step 2, the poly-A carrying cDNAs are treated with the restriction endonuclease and loose fragments are washed away. Therefore the specific method steps of Schmidt fully meet the broad claimed process step and compound library.

Schena et al discloses at page 10614, specifically the Materials and Method section, a method of producing an immobilized cDNA by hybridizing said cDNA to microarrays (library, as claimed). Therefore, the broadly claimed method

which recites a single step is fully met by the specific method steps of Schena and the product of immobilized cDNA. [Because the claimed method contains only one step, hence, the claim is subject to several interpretations of a method including the single step].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Takahishi or Schena or Schmidt in view of Keller et al (US PAT. NO. 5,656,462). Each of Takahashi, Schena and Schmidt is discussed above. Each of these references does not disclose a method of constructing a gDNA library by utilizing an immobilized sense or anti-sense portion of the gDNA library. However, Keller discloses at col. 1, line 9 up to col. 2, line 65, that a method that produces a single strand DNA immobilized on a solid support is useful for

making sense ss-cDNA from gDNA. Keller teaches that an antisene is a useful tool for understanding the biological function of a protein or mRNA whose function is unknown. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to produce from the gDNA or cDNA of each of Takahashi, Schena or Schmidt an antisense or sense portion in the manner as taught by Keller. One would have been motivated to make or study the antisense or sense portion of the DNA, whether gDNA or cDNA. An antisense or sense of a DNA would lead one to an understanding of the biological function of a protein as taught by Schena. Study of the biological function of a protein results in the discovery of a lead compound from a library that can alter the biological function of a protein.

No claim is allowed.

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit ***1639***.Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
March 6, 2003